



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS;

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Douglas D. Taylor, Ph.D. (Respondent), former Professor and Vice Chair for Research, Department of Obstetrics & Gynecology, University of Louisville School of Medicine (UL). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grants R41 CA139802 and R21 CA098166. The administrative actions, including debarment for a period of three (3) years, were implemented beginning on October 17, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Douglas D. Taylor, Ph.D., University of Louisville School of Medicine: Based on the evidence and findings of investigations conducted by UL, ORI's oversight review of UL's investigation, and additional evidence obtained and analysis conducted by ORI during its oversight review, ORI found that Dr. Douglas D. Taylor, former Professor and Vice Chair for Research, Department of Obstetrics & Gynecology, UL, engaged in research misconduct under 42 CFR part 93 in research supported by PHS funds, specifically NCI, NIH, grants R41 CA139802 and R21 CA098166.

ORI found based on a preponderance of the evidence that Respondent intentionally, knowingly, or recklessly used falsely labeled images to falsely report data in figures, and in one finding,

intentionally, knowingly, or recklessly plagiarized, reused, and falsely labeled an image to falsely report data in a figure. Respondent's research misconduct occurred in one (1) funded PHS grant application, twelve (12) unfunded PHS grant applications, and two (2) PHS-supported published papers. ORI found that these acts constitute a significant departure from accepted practices of the relevant research community. The affected papers and grant applications are:

- Patient-derived tumor-reactive antibodies as diagnostic markers for ovarian cancer. *Gynecol. Oncol.* 2009 Oct;115(1):112-20; doi: 10.1016/j.ygyno.2009.06.031 (hereafter referred to as “*Gynecol. Oncol.* 2009”).
- MicroRNA signatures of tumor-derived exosomes as diagnostic biomarkers of ovarian cancer. *Gynecol. Oncol.* 2008 Jul;110(1):13-21; doi: 10.1016/j.ygyno.2008.04.033 (hereafter referred to as “*Gynecol. Oncol.* 2008”). Corrigendum in: *Gynecol. Oncol.* 2010 Jan;116(1):153; doi: 10.1016/j.ygyno.2009.10.045.
- R01 CA152218-01, “Exosomal noncoding RNA for Lung Cancer Early Detection,” submitted to NCI, NIH, on 10/05/2009, not funded.
- RC1 HD063778-01, “Circulating exosomal microRNA in predicting preterm birth,” submitted to the National Institute of Child Health and Human Development (NICHD), NIH, on 04/29/2009, not funded.
- R41 CA144598-01, “Use of exosomal miRNA to diagnose pancreatic cancer,” submitted to NCI, NIH, on 04/10/2009, not funded.
- R01 CA132886-01A2, “Characterization of circulating lung cancer-derived exosomal miRNA,” submitted to NCI, NIH, on 03/06/2009, not funded.
- P50 CA142508-01, “University of Louisville SPORE [Specialized Program of Research Excellence] in Lung Cancer, Project 2: Exosomal MicroRNAs as Biomarkers for Lung Cancer,” submitted to NCI, NIH, on 01/23/2009, not funded.

- R21 CA135269-01A1, “miRNA methylation profiling of endometrial cancer-associated exosomes,” submitted to NCI, NIH, on 11/12/2008, not funded.
- R41 CA139802-01, “Exosomal microRNA profiles as diagnostic biomarkers of ovarian cancer,” submitted to NCI, NIH, on 05/28/2009, funded, Project Award Dates: 09/23/2009-08/31/2011.
- R01 CA132886-01A1, “Characterization of lung circulating lung cancer-derived exosomal miRNA,” submitted to NCI, NIH, on 03/05/2008, not funded.
- R41 CA135853-01, “MicroRNA signatures of tumor-derived exosomes as diagnostic biomarkers of cancer,” submitted to NCI, NIH, on 12/04/2007, not funded.
- R21 CA135269-01, “Micro RNA methylation in endometrial cancer,” submitted to NCI, NIH, on 10/16/2007, not funded.
- R21 CA132886-01, “Characterization of circulating lung cancer-derived exosomal miRNA,” submitted to NCI, NIH, on 06/04/2007, not funded.
- R41 CA131011-01, “Circulating exosomal microRNA as an Ovarian Cancer Diagnostic,” submitted to NCI, NIH, on 01/31/2007, not funded.
- R41 CA130498-01, “Serologically Defined Diagnostic and Therapeutic Response Markers for Ovarian Cancer,” submitted to NCI, NIH, on 12/01/2006, not funded.

Specifically, ORI found based on a preponderance of the evidence that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly:

- falsifying and/or fabricating research results by reusing parts of one graph to show quantitation of circulating tumor-derived exosomes from patients with varying stages of:
 - NSCLC (lung cancer) in Figure 5 of R21 CA132886-01, R01 CA132886-01A1, R01 CA132886-01A2, P50 CA142508-01, and R01 CA152218-01
 - ovarian cancer in Figure 6 of R41 CA135853-01 and R41 CA139802-01
 - pancreatic cancer in Figure 4 of R41 CA144598-01

- falsifying and/or fabricating pancreatic cancer research results in Figure 6 of R41 CA144598-01 by omitting the word “ovarian” from the label of the same image that was previously labeled as ovarian cancer tumor cells and circulating tumor-derived exosomes in Figure 8 of R41 CA139802-01
- falsifying and/or fabricating pancreatic cancer research results in Figure 7 of R41 CA144598-01 by relabeling and omitting the word “ovarian” from the label of the same image that was previously labeled as ovarian cancer tumors and exosomes from these patients in Figure 3 of *Gynecol. Oncol.* 2008 and Figure 9 of R41 CA139802-01
- falsifying and/or fabricating pancreatic cancer research results in Figure 8 of R41 CA144598-01 by relabeling and omitting the word “ovarian” from the label of the same image that was previously labeled as benign ovarian disease and ovarian cancer in Figure 4 of *Gynecol. Oncol.* 2008 and Figure 10 of R41 CA139802-01
- falsifying and/or fabricating pancreatic cancer research results in Figure 5 of R41 CA144598-01 by relabeling and omitting the word “ovarian” from the label of the same image that was previously used to show data from ovarian cancer patients in Figure 2 of *Gynecol. Oncol.* 2008, Figure 7 of R41 CA139802-01, and Figure 2 of R21 CA135269-01A1
- falsifying and/or fabricating research results by reusing a graph, first claiming to show the isolation of the miRNA fraction associated with circulating tumor-derived exosomes from an unnamed cancer in a grant application focused on ovarian cancer (Figure 6 of R41 CA131011-01) and to show the isolation of the miRNA fraction associated with circulating tumor exosomes in a subsequent grant application on endometrial cancer (Figure 6 of R21 CA135269-01); this graph was then paired with a gel image showing the RNA distribution from tumor-derived exosomes from ovarian cancer (Figure 6 of R01 CA132886-01); the figure containing the graph paired with the gel image was then used to also represent exosomes derived from:

- unnamed cancer tumors in a grant application on ovarian cancer (Figure 7 of R41 CA135853-01)
- lung cancer tumors (Figure 6 of R01 CA132886-01A1, R01 CA132886-01A2, and P50 CA142508-01)
- placentas from preterm births (Figure 3 of RC1 HD063778-01)
- falsifying and/or fabricating research results by reusing a single image to show miRNAs expressed in circulating exosomes from:
 - ovarian cancer patients in five grant applications (Figure 7 of R41 CA131011-01, Figure 7 of R21 CA135269-01, Figure 10 of R41 CA135853-01, Figure 4 of R21 CA135269-01A1, and Figure 11 of R41 CA139802-01)
 - lung cancer patients in four grant applications (Figure 8 of R21 CA132886-01 and Figure 10 of R01 CA132886-01A1, R01 CA132886-01A2, and P50 CA142508-01)
- falsifying and/or fabricating research results by reusing a single image from a non-PHS-supported paper that claimed to demonstrate the presence of antibodies that recognize normal endometrium and endometrial tumors, from the sera of women with recurrent pregnancy loss (Figure 2A and 2B in a paper published in *Fertil Steril.* 2000¹), to represent the presence of antibodies that recognize antigens from normal epithelium and ovarian tumor cell lines from patients with:
 - stage II or IV ovarian cancer in Figure 4 of R41 CA130498-01
 - stage I and stage IIIc ovarian cancer in Figure 1 of *Gynecol. Oncol.* 2009

¹*Fertil Steril.* 2000 Feb;73(2):305-13; doi: 10.1016/s0015-0282(99)00505-1 (hereafter referred to as “*Fertil Steril.* 2000”).

- plagiarizing, reusing, and relabeling an electron micrograph of melanoma derived exosomes created by a scientist and published in *Lancet*² in 2002 to falsely represent exosomes from patients with:
 - ovarian cancer in Figure 4B of R41 CA135853-01, Figure 1B of *Gynecol. Oncol.* 2008, Figure 1B of R21 CA135269-01A1, Figure 4B of R41 CA139802-01, and Figure 2B of R41 CA144598-01
 - NSCLC (lung cancer) in Figure 11B of R01 CA132886-01A1, R01 CA132886-01A2, P50 CA142508-01, and R01 CA152218-01

The following administrative actions have been implemented:

- (1) For a period of three (3) years, beginning on October 17, 2022, Respondent is debarred from participating in “covered transactions” as defined in 42 C.F.R. § 180.200 and procurement transactions covered under the Federal Acquisition Regulation (48 C.F.R. chapter 1).
- (2) Respondent is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on October 17, 2022.
- (3) In accordance with 42 CFR 93.407(a)(1) and 93.411(b), HHS will send to the pertinent journal a notice of ORI’s findings and the need for retraction or correction of:
 - *Gynecol. Oncol.* 2009 Oct;115(1):112-20; doi: 10.1016/j.ygyno.2009.06.031
 - *Gynecol. Oncol.* 2008 Jul;110(1):13-21; doi: 10.1016/j.ygyno.2008.04.033

Dated: November 22, 2022.

Wanda K. Jones,

Acting Director, Office of Research Integrity,

²*Lancet* 2002 Jul 27;360(9329):295-305; doi: 10.1016/S0140-6736(02)09552-1 (hereafter referred to as “*Lancet* 2002”).

Office of the Assistant Secretary for Health.

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